REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 57-61, 71-83, 93-101, 103 and 113-118 are pending in this application. Claims 57-58, 60, 71, 77, 81-83, 93 and 100-101 are amended. Claims 113-118 are newly added. Support for the newly added claims is found throughout the specification, in particular, page 17, lines 1-4, and therefore, no new matter has been added. No claims have been cancelled. Claims 57, 60, 81, 83, 100 and 101 are the independent claims.

Example Embodiments of the Present Application

Independent claim 57 recite a device for promoting regeneration of an injured nerve including a nerve encasement structure, and a plurality of biodegradable guiding fibers, wherein the material of the nerve encasement structure and the material of the guiding fibers each comprises at least one biodegradable polymer, wherein said at least one polymer comprised in the material of the guiding fibers presents an average molecular weight which is lower than a molecular weight of said at least one polymer comprised in the material of the nerve encasement structure, wherein the material of the nerve encasement structure comprises polyhydroxybutyrate (PHB) and the material of the guiding fibers comprises PHB and the PHB average molecular weight of the nerve encasement structure is within the range of 100,000 to 250,000 daltons and the PHB average molecular weight of the guiding fibers is within the range of 50,000 to < 250,000 daltons, and wherein at least a majority of the

guiding fiberspresent an *in vivo* degradation time (t_1) being less than the time required for establishing regenerated contact between ends of an injured nerve (t_c) using the device for said regeneration. Independent claims 60, 81, 83, 100 and 101 recite similar features.

Example non-limiting embodiments of this feature are discussed, for example, in page 6, lines 26-31, page 7, line 18 to page 8, line 30 of the instant specification.

As is illustrated in the present application, the difference between the *in vivo* degradation times t_1 and t_2, and their respective relations to t_c and/or t_r are responsible for the improved nerve regeneration process achieved. The nerve regeneration process is improved with respect to regeneration time and/or function of the restored nerve. Furthermore, the nerve encasement structure allows to some extent the penetration of degrading factors even before the nerve encasement structure is essentially disintegrated, thus further enhancing the difference in *in vivo* degradation times between the nerve encasement structure and the guiding fibers.

Rejections under 35 U.S.C. § 103

Williams in view of Hansson and Seckel

Claims 57-61, 71-83, 93-101 and 103 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,548,569 to Williams et al. (hereinafter "Williams") in view of U.S. Patent No. 5,656,605 to Hansson et al. (hereinafter "Hansson") and U.S. Patent No. 5,584,885 to Seckel. Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner states that since the structures and compositions of the nerve guides disclosed by Williams are the same as those of the present application, and the range of molecular weight overlaps with the claimed range, the prior art would also have the same properties of t_1, t_2, t_c, and t_r as recited in the claims (Office Action, page 7, first paragraph). Applicants respectfully disagree.

Applicants submit that t_c and t_r represent time periods related to the nerve regeneration process, and t_c and t_r are properties of the nerve to be regenerated. Corresponding time periods can be defined for any injured nerve, independent of the presence or absence of a nerve regeneration device (although actual values of t_c, and t_r may be different). On the other hand, t_1 and t_2 define the *in vivo* degradation times of the biodegradable nerve encasement structure or the biodegradable guiding fibers, respectively. The time period t_1 is always less than t_2 as recited in independent claims 57, 60, 81, 83, 100 and 101.

Regarding the cited references, the structures and compositions of the nerve guides of Williams are not the same as those recited in independent claims 57, 60, 81, 83, 100 and 101. Further, Williams fails to indicate that the molecular weights of the different structures of the nerve guide should invariably be selected from different parts of that range, or otherwise be composed of materials presenting different *in vivo* degradation times. Hence, Applicants respectfully submit that the nerve guides of Williams would not

have the same *in vivo* degradation times t_1 and t_2, related to t_c and/or t_r, as recited in independent claims 57, 60, 81, 83, 100 and 101.

Hansson teaches that guide thread filament materials may consist of materials similar or identical to the materials used for a guide tube (col. 4, lines 32-34). However, Hansson is not concerned with molecular weights or degradation times of these materials. Furthermore, the Examples use non biodegradable materials such as silicone rubber and nylon. Therefore, Applicants submit that the device disclosed in Hansson would not have the same *in vivo* degradation times t_1 and t_2 as recited in independent claims 57, 60, 81, 83, 100 and 101.

Seckel does not teach the use of a plurality of guiding fibers in a device for the regeneration of an injured nerve as recited in independent claims 57, 60, 81, 83, 100 and 101, but rather for the regeneration of axon subchambers 60 (See col. 15 lines 1-17). In addition, Applicants submit that there is no indication in Seckel that the matrix element 58b should present an *in vivo* degradation fulfilling certain criteria, or that the matrix element should be degraded at any particular point in time. Hence, the device of Seckel would not present the same *in vivo* degradation times t_1 and t_2 as recited in independent claims 57, 60, 81, 83, 100 and 101.

In view of the above, Applicants respectfully submit that none of the cited references disclose a nerve guide having *in vivo* degradation times fulfilling the relations as recited in independent claims 57, 60, 81, 83, 100 and 101.

Finally, on page 5 of the Office Action, the Examiner refers to pages 19-21 of our previous response stating that the applicant argues that the cited references do not render the invention obvious because the cited references provide no suggestion that a material of low molecular weight would degrade more quickly than the corresponding material of high molecular weight under identical conditions *(OA, p. 5)*. Applicants believe that this is a misinterpretation by the Examiner of the Applicants' arguments. Applicants submit that there is no suggestion in the cited references that a material of low molecular weight (indeed degrading more quickly than the corresponding material of high molecular weight under identical conditions) is desirable for certain parts of a nerve conduit (page 20 of previous response). Therefore, a person of ordinary skill in the art would have no incentive to differentiate the molecular weights of the nerve encasement structure and the guiding fibers as recited in independent claims 57, 60, 81, 83, 100 and 101. That is, the skilled person would see no reason for not using the same material (e.g., having the same molecular weight) for the encasement structure and the guiding fibers. On the contrary, it would seem reasonable to the skilled person to use the same material in order to keep it simple, e.g. for manufacturing purposes.

Claims 58-59, 61, 71-80, 82, 93-99, 103 and newly added claims 113-118, dependent on independent claims 57, 60, 81, 83, 100 and 101, are patentable for the reasons set forth above as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 57-61, 71-83, 93-101 and 103 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

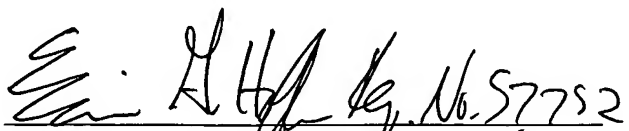
In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By  Reg. No. 57752

Donald J. Daley, Reg. No. 34,313
P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/EGH:ljs